O-18

OCCLUTECH DUCT OCCLUDER—INITIAL HUMAN EXPERIENCE

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Objective: To evaluate the feasibility, safety, and efficacy of the new Occlutech duct occluder for closure of patent ductus arteriosus (PDA).
Background: The device is a self-shaping device made of Nitinol wires, consisting of a retention disc and shank joined by a tether theoretically to allow articulation between the two. Polyethylene terephthalate (PET) patches are integrated ductally in the shank to assure a better obturation of the duct defect. Two subsequent design changes were made, the final being the removal of the tether to ensure correct position of the shank in the PDA.
Methods: A prospective non-randomized pilot study conducted from November 2011 to September 2012. Patients weighing less than 6 kg or those with associated cardiac anomalies that required cardiac surgery were excluded. Large PDA was defined as narrowest PDA diameter size $\geq$3.5 mm associated with symptomatic heart failure. All PDA were closed following the standard method technique. All devices were delivered via 5/6 Fr sheath. All patients were followed up by transthoracic echocardiography for 24 hr, 1 month (earlier if indicated), 3 month, 6 month, and 12 month after implantation.
Results: Twenty-six patients with type A PDA (16 females, 10 males), with a median age of 23 months (6 months–36 years) and median weight 9.2 kg (6–56 kg) were included .The median PDA narrowest diameter was 2.7 mm (1.8–4.6 mm). Of included patients six patients had large PDA as defined. Mean fluoroscopy time was 9.2 min. All patients with large PDA had significant residual shunt immediately postimplantation. Two patients (PDA size 4.4 mm and 3 mm) needed removal of the earlier device design due to malposition following release and AGA occluder was implanted. With current design, five patients with large PDA showed significant residual shunt through the device despite correct position, which became insignificant within 1 to 2 weeks.
Complications: There was no device embolization, hemolysis, obstruction to left pulmonary artery or descending aorta in all cases. One patient developed insignificant tricuspid regurgitation during retrieval of a released device.
Conclusion: Occlutech ductal occluder is safe, feasible, and effective. However patients with large PDA tended to have delayed complete closure.